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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/074,754

02/13/2002

Daniel L. Marks

96,886-L

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07/24/2006

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EXAMINER

CHANDRA, GYAN

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                     |  |
|------------------------------|--------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/074,754 | <b>Applicant(s)</b><br>MARKS ET AL. |  |
|                              | <b>Examiner</b><br>Gyan Chandra      | <b>Art Unit</b><br>1646             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15 is/are pending in the application.  
     4a) Of the above claim(s) 1-4 and 7-15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5-6 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |  |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____  |

## **DETAILED ACTION**

### **Status of Application, Amendments, And/Or Claims**

Claims 1-15 are pending. Claims 1-4 and 7-15 are withdrawn from further consideration as being drawn to a nonelected Invention.

Claims 5 and 6 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Response to Arguments***

Applicant's arguments, see Remarks, filed 5/11/2006, with respect to rejection of claims 5-6 under 35 U.S.C. 112, first paragraph-written description have been fully considered and are persuasive. The rejection of claims 5-6 under 35 U.S.C. 112, first paragraph-written description has been withdrawn.

The rejection of claims 5-6 under 35 U.S.C. 112, first paragraph-enablement is withdrawn in view Applicant's arguments filed on 5/11/2006.

The rejection of claims 5-6 under 35 U.S.C. 102(e) as being anticipated by Bednarek, is withdrawn in view of Applicants' arguments filed on 5/11/2006.

### **Rejections maintained**

Claims 5-6 remain rejected under 35 U.S.C. 102(e) as being anticipated by Cone et al.

The claims are drawn to a method of preventing a pathological feeding behavior, cachexia in an animal comprising administering an effective amount of a mammalian melanocortin 4 (MC-4) receptor antagonist to the animal.

Applicants argue that although Cone et al teach the administration of a compound to an animal for stimulating feeding behavior, they do not teach each and every limitation of the claimed "pathological eating behavior", and the teachings of the reference are not directed towards cachexia.

Applicants' arguments have been fully considered but they are not persuasive because Cone et al teach a MC-4 receptor antagonist as stimulator of feeding behavior in an animal (column 5, lines 40-43) and they further teach that antagonists of the receptor can be used for treating the pathological disorder cachexia which occurs in cancer patients (column 12, lines 28-30 and col. 25, lines 55-62). Therefore, Cone et al., explicitly encompass all the limitations of instantly claimed invention.

Claims 5-6 remain rejected under 35 U.S.C. 102(e) as being anticipated by Dooley et al.

The claims are drawn to a method of preventing a pathological feeding behavior, cachexia in an animal comprising administering an effective amount of a mammalian MC-4 receptor antagonist to the animal.

Applicants argue that Dooley et al do not characterize the pathology of rats as cachetic and that the short-term administration of HP-228 to a rat would not create an equivalent of a "pathological feeding behavior" or cachexia.

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Applicants' arguments have been fully considered but they are not persuasive because Dooley et al. teach that the antagonist #P467 can be used to treat cachexia (col. 6, lines 34-40, col. 7, lines 60-65, col. 8, lines 50-55). Therefore, Dooley's method of administering a MC-4 receptor antagonist anticipates the instantly claimed method of treating cachexia in an animal.

### ***Conclusion***

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gyan Chandra whose telephone number is (571) 272-2922. The examiner can normally be reached on 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gyan Chandra, Ph.D.  
Art Unit 1646  
17 July 2006  
Fax: 571-273-2922

  
**EILEEN B. O'HARA**  
PRIMARY EXAMINER